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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/581,789	06/06/2006	Laurent Denu	4662-184	5503

23117 7590 09/18/2007
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EXAMINER	
WALLENHORST, MAUREEN	
ART UNIT	PAPER NUMBER
1743	
MAIL DATE	DELIVERY MODE
09/18/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/581,789	DENU ET AL.	
	Examiner	Art Unit	
	Maureen M. Wallenhorst	1743	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) 1-9 is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) 1-9 is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☒ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☒ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date 6/6/06.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

1. Receipt is acknowledged of papers submitted under 35 U.S.C. 119(a)-(d), which papers have been placed of record in the file.

2. The oath or declaration is defective. A new oath or declaration in compliance with 37 CFR 1.67(a) identifying this application by application number and filing date is required. See MPEP §§ 602.01 and 602.02.

The oath or declaration is defective because: The title of the invention is missing in the declaration.

3. Applicant is reminded of the proper language and format for an abstract of the disclosure.

The abstract should be in narrative form and generally limited to a single paragraph on a separate sheet within the range of 50 to 150 words. It is important that the abstract not exceed 150 words in length since the space provided for the abstract on the computer tape used by the printer is limited. The form and legal phraseology often used in patent claims, such as "means" and "said," should be avoided. The abstract should describe the disclosure sufficiently to assist readers in deciding whether there is a need for consulting the full patent text for details.

The language should be clear and concise and should not repeat information given in the title. It should avoid using phrases which can be implied, such as, "The disclosure concerns," "The disclosure defined by this invention," "The disclosure describes," etc.

4. The abstract of the disclosure is objected to because of the inclusion of legal phraseology such as "comprises". Correction is required. See MPEP § 608.01(b).

5. The disclosure is objected to because of the following informalities: Applicants are requested to provide headings in the specification for the "Background of the Invention", the "Summary of the Invention", the "Brief Description of the Drawings" and the "Detailed Description of the Invention". In addition, there is no brief description of the drawings in the specification, and therefore, Applicants are required to amend the specification in order to provide one.

Appropriate correction is required.

6. Claims 1-9 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

On line 3 of claim 1, the phrase "the feed sample" lacks antecedent basis. In part a) of claim 1, the phrase "having a polarity similar to but different from 25-hydroxycholecalciferol" is indefinite and vague since it is not clear what degree of similarity in polarity to the 25-hydroxycholecalciferol the internal standard must have. The metes and bounds of this phrase are not clear, and it is unclear what patent protection is sought by this phrase. One of ordinary skill in the art would not know whether a particular internal standard having a polarity similar to but different than 25-hydroxycholecalciferol would qualify for use in the method since they would not know whether the polarity would be close enough to or different enough from 25-hydroxycholecalciferol. In part b) of claim 1, the phrase "the aqueous dispersion" lacks antecedent basis. In part d) of claim 1, the phrase "the fractions containing 25-hydroxycholecalciferol" lacks antecedent basis. In part f) of claim 1, the phrase "the MS peak areas" lacks antecedent basis.

In claim 6, the recitation of "Hypersil Si 60" is indefinite since the recitation of materials covered by trademarks or trade names is not permitted in U.S. claims since these materials are subject to change over time.

On line 2 of claim 7, the phrase "the analytical HPLC" lacks antecedent basis and is indefinite since it is not clear whether this refers to the HPLC performed in part c) or part e) of claim 1. On line 3 of claim 7, the phrase "the substances to be measured" is indefinite since it is not clear whether these substances are the 25-hydroxycholecalciferol being determined in the

method of independent claim 1. On lines 3-4 of claim 7, the phrase "the intrinsic analytical column" lacks antecedent basis and is indefinite since this phrase does not make proper sense in the context of claim 7. It is not clear whether the recited chromatography system comprises both a trapping column and an intrinsic analytical column.

On lines 1-2 of claim 8, the phrase "the analytical HPLC" lacks antecedent basis and is indefinite since claim 8 depends from claim 4, and claim 4 recites the semipreparative HPLC. Regarding claim 8, the phrase "such as" renders the claim indefinite because it is unclear whether the limitations following the phrase are part of the claimed invention. See MPEP § 2173.05(d). On line 2 of claim 8, the recitation of "Aquasil C18" is indefinite since the recitation of materials covered by trademarks or trade names is not permitted in U.S. claims since these materials are subject to change over time.

7. Claim 1 would be allowable if rewritten or amended to overcome the rejection(s) under 35 U.S.C. 112, 2nd paragraph, set forth in this Office action since none of the prior art of record teaches or fairly suggests a method for the quantitative determination of 25-hydroxycholecalciferol in an animal feed sample by dispersing an animal feed sample in water and adding an internal standard compound thereto, extracting the aqueous sample with tert butyl methyl ether, submitting the ether extract to HPLC, collecting fractions eluting from the HPLC column containing 25-hydroxycholecalciferol and internal standard, submitting the fractions collected to another HPLC column combined with mass spectrometry (MS), measuring MS peak areas of 25-hydroxycholecalciferol and the internal standard, and calculating the amount of 25-hydroxycholecalciferol in the feed sample by computing the MS peak areas measured. Specifically, none of the prior art of record teaches or fairly suggests determining 25-

hydroxycholecalciferol in an animal feed sample by dispersing the sample in water along with an internal standard and extracting the aqueous dispersion with tert butyl methyl ether before performing HPLC separation and detection by mass spectrometry.

8. Claims 2-9 would be allowable if rewritten to overcome the rejection(s) under 35 U.S.C. 112, 2nd paragraph, set forth in this Office action and to include all of the limitations of the base claim and any intervening claims for the same reasons as given above.

9. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

Please make note of: Murray et al and Edwards Jr., who teach of animal feed mixtures containing 25-hydroxycholecalciferol; Krammer et al who teach of pet food containing 25-hydroxycholecalciferol; Stark et al who teach of 25-hydroxycholecalciferol as a dietary supplement in an animal feed; Clarke et al (2006/0228809 and 2006/0228808) who teach of a method for detecting vitamin D metabolites by mass spectrometry; Singh et al who teach of a method for determining the amount of vitamin D compounds in a sample using LC-MS/MS techniques; and Luca who teaches of the measurement of 25-hydroxycholecalciferol in serum from animals. It is noted that the effective filing dates of the publications to Clarke and Singh et al are after the foreign priority date of the instant application.

10. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Maureen M. Wallenhorst whose telephone number is 571-272-1266. The examiner can normally be reached on Monday-Thursday from 6:00 AM to 4:30 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jill Warden, can be reached on 571-272-1267. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Maureen M. Wallenhorst
Primary Examiner
Art Unit 1743

mmw

September 12, 2007

Maureen M. Wallenhorst
MAUREEN M. WALLENHORST
PRIMARY EXAMINER
GROUP [redacted] 1700